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(12) UK Patent Application (19) GB (11) 2 379 393 (13) A

(43) Date of A Publication 12.03.2003

(21) Application No 0214808.8

(22) Date of Filing 27.06.2002

(30) Priority Data
(31) 0119124 (32) 04.08.2001 (33) GB

(51) INT CL^7
A61M 16/04

(52) UK CL (Edition V)
A5R RGEX

(56) Documents Cited
GB 2310605 A
US 5058580 A
EP 0371752 A1
US 5042475 A

(58) Field of Search
INT CL^7 A61M
Other: ONLINE: EPODOC, WPI, JAPIO

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(54) Abstract Title
TRACHEOSTOMY TUBE OBDURATOR

(57) A tracheostomy tube obdurator 2 has a straight handle 20 of a rigid plastics material moulded onto a curved midsection 21. The midsection comprises an outer shaft 29 of a polyurethane and an inner rigid metal tube 28. The outer shaft 29 continues forwardly beyond the end of the metal tube 28 to provide a flexible, tapering patient end tip 22. When inserted in a tracheostomy tube 1, the handle 20 protrudes from the machine end 13, the midsection 21 retains the tube in the desired curvature for insertion in the patient, and the patient end provides a flexible tip 22 that protrudes by about three times the external diameter of the tube.

Fig.1.

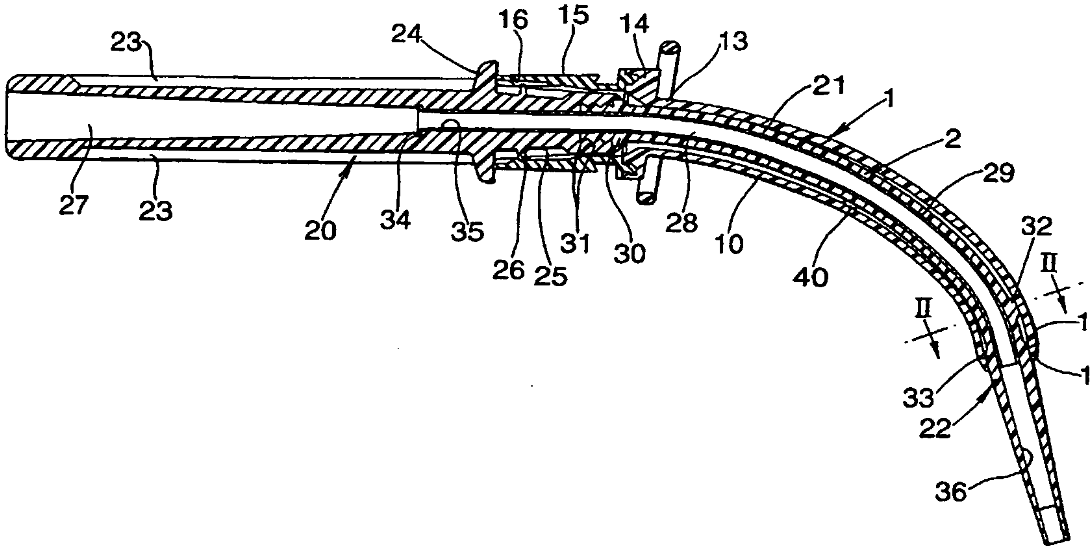

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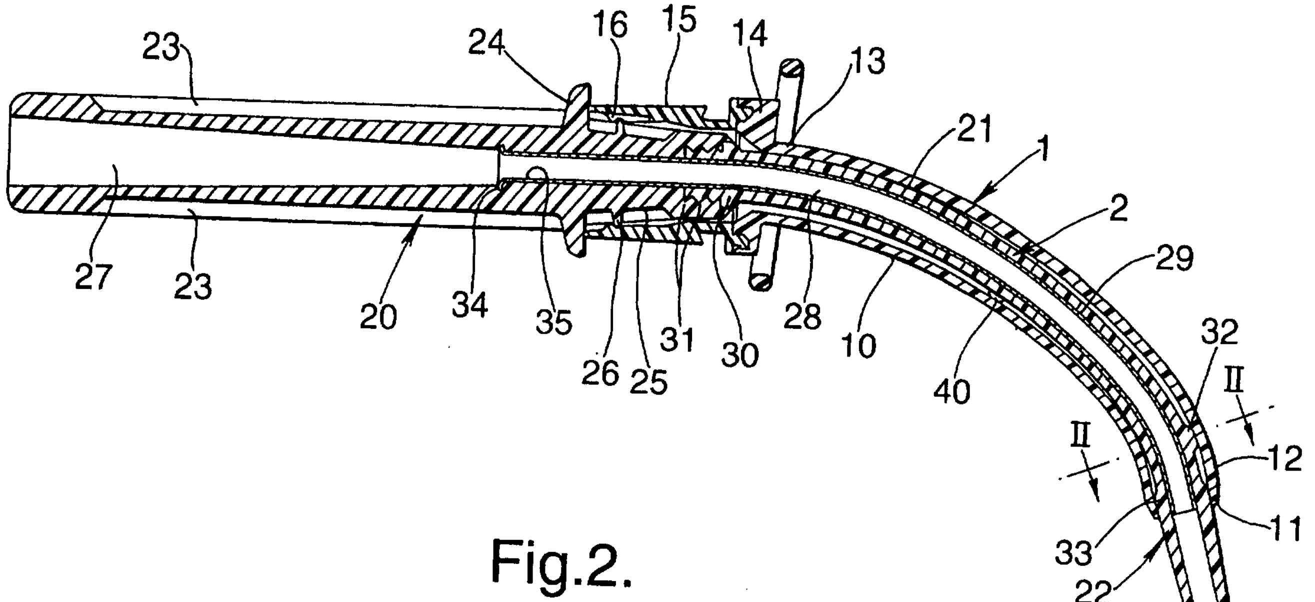
Fig.1.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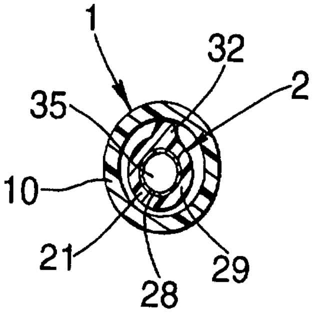
II

Fig.2.



INTRODUCERS AND ASSEMBLIES

This invention relates to introducers and to assemblies including introducers.

Tracheostomy tubes may be inserted into position in the trachea using an introducer inserted within the tube. The introducer has a pointed end protruding from the patient end of the tube to ease insertion of the tip of the tube through the tissues of the surgical opening into the trachea. The introducer also provides additional stiffness to prevent bending of the tube as a result of the forces used to push it into position. The introducer may protrude from the machine end of the tube sufficiently to form a handle by which the assembly can be gripped. Often, the tracheostomy tube is inserted along a guidewire or a small-bore catheter previously positioned using a guidewire. Where this technique is used, the introducer has a passage along its length along which the guidewire and catheter can extend. Examples of introducers are described in EP0590084, GB2224213, GB2341102 and GB2350061.

It is an object of the present invention to provide an alternative introducer and assembly including an introducer.

According to one aspect of the present invention there is provided an introducer for a medical tube, the introducer having a first, relatively flexible end arranged to protrude from a first, patient end of the tube, a relatively rigid midsection arranged to extend within the tube and a second end arranged to protrude from a second end of the tube.

The second end of the introducer may be relatively rigid. The introducer is preferably of plastics material and has a metal insert extending along the midsection. The second end is preferably of a different material from the remainder of the introducer, such as ABS plastics material. The second end and the midsection may be joined with one another by moulding. The midsection is preferably curved along its length. The introducer preferably has a passage along its length. The second end may be shaped with gripping formations and the first end is preferably tapered. The length of the first end is preferably greater than twice its diameter at its largest part and is preferably greater than approximately three times its diameter. The introducer may have a projection on its surface at a location along the midsection, which may be located towards the forward end of the midsection and shaped to maintain a circular shape at the patient end of the tube.

According to another aspect of the present invention there is provided an assembly of a tube and an introducer according to the above one aspect of the invention, the introducer being inserted within the tube with the first end of the introducer protruding from the patient end of the tube.

The first end of the introducer preferably protrudes from the patient end of the tube by a distance greater than twice the external diameter of the tube. The tube is preferably a tracheostomy tube.

An introducer for a tracheostomy tube and an assembly of an introducer and tracheostomy tube will now be described, by way of example, with reference to the accompanying drawing, in which:

Figure 1 is a sectional side elevation view of the assembly; and

Figure 2 is an enlarged transverse sectional view of the assembly along the line II-II.

The assembly comprises a tracheostomy tube 1 and an introducer 2 inserted within the tube.

The tracheostomy tube 1 is of conventional form having a tubular shaft 10 moulded from a bendable plastics material and having an atraumatic, slightly tapered tip 11 at its patient end 12. The shaft 10 is curved along its length although its natural curve has a smaller radius than shown in Figure 1 where the tube has been straightened slightly by the introducer 2. At its rear or machine end 13, the tube 1 has a flange 14 moulded integrally with the shaft 10 and a female 15mm ISO tapered coupling 15 of a harder plastics material joined with the flange.

The introducer 2 comprises three sections along its length: a rear or machine-end handle 20, a midsection 21 and a forward or patient-end section 22. The handle 20 is straight and substantially cylindrical, being about 90mm long and 13 mm in diameter. Four gripping ribs 23 extend longitudinally along the handle and terminate towards its forward end at an annular flange 24 projecting radially outwardly. The diameter of the flange 24 is greater than the external diameter of the coupling 15 so that it abuts the end of the coupling when the introducer 2 is inserted in the tube 1. Forwardly of the flange 24, the handle 20 has a short, slightly tapered region 25 with a second, smaller flange 26. The dimensions of the tapered region 25 are such that it can extend freely within the coupling 15. The diameter of the second flange 26 is such that it catches on the forward side of a shallow internal lip 16 within the coupling. A passage or bore 27 extends along the length of the handle 20, the bore being tapered from its rear end until just rearwardly of the larger flange 24. The handle 20 is moulded from a hard plastics material, such as ABS, so that it is rigid

The forward end of the handle 20 is moulded about the rear end of a stainless steel tube insert 28, which extends forwardly along the midsection 21. An outer shaft 29 of a soft plastics material such as polyurethane extends along the outside of the insert 28 beyond its forward end to form the patient-end section 22. At its rear end 30, the plastics shaft 29 is shaped with formations that key it into the forward end of the handle 20. The midsection 21 is curved along its length and is rigid because of the presence of the metal insert 28. The midsection 21 has a circular section with an external diameter slightly less than the internal diameter of the tube 1. The midsection 21 may have an optional surface formation 32 close to its forward or patient end. The surface formation takes the form of a hemispherical bump or projection 32 on the external surface on the outside of the curve. The purpose of this projection 32 will be described later. The midsection 21 may also or alternatively have a shallow external annular rib 40 about half way along its length, to reduce friction with the inside of the tube 1.

The patient-end section or tip 22 is a continuation of the plastics shaft 29. The rear end 33 of the tip 22 is enlarged slightly to be equal to or greater than the internal diameter of the tube 1 and it tapers along its length to a reduced diameter of about 3mm. The tip 22 is about 33mm long, it is straight and all but the rear 3mm or so of the tip projects from the tube 1. The length of flexible tip 22 projecting from the tube 1 is equal to about three to four times the external diameter of the shaft 29 and is at least twice the external diameter of the tube, preferably being about three times its diameter. The total length of the flexible tip 22 is, therefore, greater than about three times the diameter at its largest part.

The bore 27 along the handle 2 opens into the rear of the metal insert 28 via a small external flare 34 on the insert and forms a continuation with the bore 35 along the insert. The bore 35 of the insert 28 opens at its forward end into a bore 36 along the tip 22.

The shaft 29 is moulded first and then assembled onto the metal insert 28. The handle 20 is then moulded about the rearwardly projecting end of the insert 28 and the rear end 30 of the shaft 29. This ensures a good bond between the different components of the introducer.

The radius of curvature of the midsection 21 of the introducer 2 is selected to be the best for insertion of the tracheostomy tube 1 and is larger than the natural curvature of the tube, that is, without the introducer. The natural curvature of the tracheostomy tube 1 is chosen to be the best for the anatomy of the patient after insertion. The introducer 2, therefore, slightly straightens the tube 1 when it is inserted. When fully inserted, the rear flange 24 abuts the rear end of the coupling 15 and the forward flange 26 catches on the forward side of the lip 16, thereby resisting slightly removal of the introducer 2. The rear 33 of the patient end 22 locates as a close fit within the patient end 12 of the tube 1 so that there is a substantially smooth, stepless transition between the introducer 2 and the tube. Depending on the shape of the introducer 2 and the tube 1, the action of straightening a tube during insertion of an introducer may tend to distort the tube from a circular to a slightly oval section. This is undesirable because it forms a gap between the tip of the tube and the introducer, which could catch on tracheal tissue during insertion. The projection 32, where present, serves to reduce the force between the introducer 2 and the tip of the tracheostomy tube 1 by deflecting the tube at a point sufficiently behind the tip to avoid deformation of the circular opening at the end of the tube. The need for the projection 32 can be avoided by altering the curvature of the introducer at the forward end of the midsection.

The assembly of the introducer 2 and tube 1 is used in the usual way in conjunction with a guidewire and a small-bore catheter (not shown) having one end located in the patient's trachea. The assembly of the tracheostomy tube on the introducer is threaded over the catheter and the assembly is slid forwardly so that the patient end of the assembly passes smoothly through the tracheostomy into the trachea. The long, flexible tip 22 of the introducer 2 forms a leader that ensures the assembly follows the guidewire and catheter to the correct location within the trachea.

It will be appreciated that the invention is not confined to tracheostomy tubes but could be used with other medical tubes.

CLAIMS

1. An introducer for a medical tube, wherein the introducer has a first, relatively flexible end arranged to protrude from a patient end of the tube, a relatively rigid midsection arranged to extend within the tube and a second end arranged to protrude from the second end of the tube.

2. An introducer according to Claim 1, wherein the second end of the introducer is relatively rigid.

3. An introducer according to Claim 1 or 2, wherein the introducer is of plastics material and has a metal insert extending along the midsection.

4. An introducer according to any one of the preceding claims, wherein said second end is of a different material from the remainder of the introducer.

5. An introducer according to Claim 4, wherein said second end is of ABS plastics material.

6. An introducer according to any one of the preceding claims, wherein said second end and the midsection are joined with one another by moulding.

7. An introducer according to any one of the preceding claims, wherein the midsection is curved along its length.

8. An introducer according to any one of the preceding claims, wherein the introducer has a passage along its length.

9. An introducer according to any one of the preceding claims, wherein said second end is shaped with gripping formations.

10. An introducer according to any one of the preceding claims, wherein said first end is tapered.

11. An introducer according to Claim 10, wherein the length of said first end is greater than twice the diameter at its largest part.

12. An introducer according to Claim 11, wherein the length of said first end is greater than approximately three times the diameter of said first end at its largest part.

13. An introducer according to any one of the preceding claims, wherein the introducer has a projection on its surface at a location along the midsection.

14. An introducer according to Claim 13, wherein the projection is located towards the forward end of the midsection and is shaped to maintain a circular shape at the patient end of the tube.

15. An introducer substantially as hereinbefore described with reference to the accompanying drawing.

16. An assembly of a tube and an introducer according to any one of the preceding claims, the introducer being inserted in the tube with said first end of the introducer protruding from the patient end of the tube.

17. An assembly according to Claim 16, wherein said first end of the introducer protrudes from the patient end of the tube by a distance greater than twice the external diameter of the tube.

18. An assembly according to Claim 17, wherein said first end of the introducer protrudes from the patient end of the tube by a distance substantially three times the external diameter of the tube.

19. An assembly according to any one of Claims 16 to 18, wherein the tube is a tracheostomy tube.

20. A tracheostomy tube assembly substantially as hereinbefore described with reference to the accompanying drawing.

21. Any novel and inventive feature or combination of features as hereinbefore described.

The Patent Office

Application No:	GB 0214808.8	**Examiner:**	Dr. Simon Grand
Claims searched:	1-20	**Date of search:**	6 January 2003

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X, Y	X:1, 2, 6, 7, 9, 10-12 and 16-20. Y:8	EP 0371752 A1	(SHETTY) See figs. and col.2 l. 44-col.3 l.27.
Y	8	GB 2310605	(SMITHS INDUSTRIES) See figs. and page 3 paragraph 2.
A		US 5058580	(HAZARD) See figs.
A		US 5042475	(LABOMBARD) See figs. and col.2 ll.53-63

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^T:

Worldwide search of patent documents classified in the following areas of the IPC^7:

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The following online and other databases have been used in the preparation of this search report:

ONLINE: EPODOC, WPI, JAPIO